HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2749n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 1999

WARNING LETTER – WITH AUTOMATIC DETENTION

Ref:OC:I1-1825

via FEDERAL EXPRESS

President
Likelisa Enterprises Co., Ltd.
3F, No. 40-1 Sec. 3
Po An Street, Shu Lin Chien
Taipei Hsien, Taiwan
R.O.C.

Mr. Robert Liu, General Manager
Lei-Feng Laser Industrial Co., Ltd.
4F, No. 11, Alley 8, Lane 151 Sec. 2
Chung Shan Rd., Shu Lin Jan
Taipei Hsein, Taiwan
R.O.C.

Mr. Robert Liu, General Manager
Lei-Fond Laser Industrial Co., Ltd.
4F, No. 11, Alley 8, Lane 151 Sec. 2
Chung Shan Rd., Shu Lin Jan
Taipei Hsein, Taiwan
R.O.C.

Gentlemen:

This letter is to advise you of items of noncompliance with the Federal performance standard for laser products 21 CFR 1040.10 and 1040.11, encountered during laboratory testing of the radiation output and the labeling of nine pen style laser pointers collected from a shipment of pointers consigned to California Gift Center, Inc., 4334 South Santa Fe Ave., Vernon, California 90058, Attn: Mr. Thomas Wu. Shipping documents (copy enclosed) for these pointers included a notation that they were Class IIIa, model SY-202C series and were associated with FDA accession no. 9710662-00. This number had been assigned to a laser product report submitted by Lei-Feng Laser Industrial Co., Ltd., 4F, No. 11, Alley 8, Lane 151, Sec. 2, Chung Shan Rd., Shu Ling, Taipei Hsein, Taiwan, R.O.C. We received, by a letter dated December 31, 1998, an annual report from Mr. Robert Liu, General Manger, Lei-Fond Industrial Laser Company, Ltd., at the same address as Lei-Feng Industrial Laser Co., Ltd. That report (accession No. 9930449-00) summarized quality control and testing records for production of laser pointers identified as Model SY-202C. The summary identified these pointers as having the accession no. 9710662-00. Our files do not show that Lei-Fond has submitted a report for a laser product, and there is no description of a relationship between Lei-Feng and Lei-Fond. Also, our records do not show that Likelisa Enterprise Co., Ltd., has submitted a laser product report. Please explain the relationship between these firms.

The following items of noncompliance are applicable to eight pointers tested:

1. 21 CFR1040.10(c) and 1040.10(d) - Classification of laser products: Two of the eight pointers were misclassified in that the radiation output of these two units exceeded the Class IIIa limit of 5 mW. As a result, these two units are Class IIIb and failed to comply with the requirements of the standard applicable to Class IIIb laser products. It is noted that one pointer failed to operate.

2. 21 CFR 1040.11(b) - Alignment laser products: Laser pointers are surveying, leveling and alignment laser products and are limited to a maximum radiation output of 5 mW. These two units were noncompliant with this requirement.

3. 21 CFR 1010.2 - Certification: Labels or tags certifying that the products comply with the standard, were neither affixed to the pointers as required nor included in the user information.

4. 21 CFR 1010.3 - Identification: Labels containing the identification information specified in the regulations were neither affixed to the pointers nor included in the user information.

5. 21 CFR 1040.10(g) - Labeling requirements: The required warning logotype label was not affixed to the pointers as required by 21 CFR 1040.10(g)(10). Inclusion of this label in the package with instructions for the purchaser to affix the label to the product is not acceptable. The manufacturer must permanently affix this label to the products at the time of certification. Further, the products must be in full compliance with the standard at the time they are presented for entry into U.S. commerce. The holographic format and the small print of the wording on the warning logotype label included in the packaging makes this label unreadable. The wording on labels must be of a sufficient size to be readable by a person with normally corrected vision without magnification. The format should not be of a design to hinder readability. The warning logotype supplied with the pointers was incorrect in that it stated that the output of the pointers was <3 mW. Radiation output of seven of the eight pointers tested exceeded 3 mW.

6. 21 CFR 1040.10(g)(5) - Aperture label: Aperture labels were not affixed to the pointers as required.

7. 21 CFR 1040.10(b) - User information: The warning logotype reproduced in the "User Instructions" was incorrect. The "Caution" warning logotype shown identified the pointers as being Class II laser product having less than 1 mW output when the intended class of the pointers was Class IIIa with an output of less than 5 mW. Further, the location on the pointers of the required warning

label was not shown in these instructions as required by 21 CFR 040.10(h)(iii). The location of the aperture of the pointers was incorrectly indicated as being from the writing end of the pen.

We understand that these products were refused entry and were not introduced into commerce in the United States. Therefore, we will not require submission of notification or a corrective action plan (CAP) for that particular shipment.

However, you are hereby advised that section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

Based on the non-compliances cited above, it is clear that the manufacturer(s) of these laser pointers have failed to establish and maintain quality assurance and testing programs that assure compliance of laser products with the standard. In view of the fact that we are unable to establish who actually manufactured these pointers, by this letter, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration disapproves the quality control and testing program(s) for all laser products produced by or for Likelisa Enterprise Co., Lei-Feng Laser Industrial Co., Ltd., and Lei-Fond Laser Industrial Co., Ltd.

This disapproval means that your firms are prohibited by Section 534(h) and 538 of the Act from:

1. Certifying laser products manufactured under the disapproved testing program,

2. Introducing or importing laser products into the U.S. commerce which bear false and misleading certification, that is products certified under a testing program which has been disapproved, and

3. Introducing or importing into U.S. commerce any product that does not have a certification label permanently affixed to the product as required by 21 CFR 1010.3.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U.S. of any electronic product if it appears that the product fails to comply with the Act, that the subject products do not comply with the performance standard, and the testing program is not in accordance with good manufacturing practices. Therefore, we have requested U.S. Customs Service to refuse entry of all laser products identified as being produced by or for either Likelisa Enterprise Co., Ltd., Lei-Fond Laser Industrial Co., Ltd., or Lei-Feng Laser Industrial Co., Ltd.

If you intend to export laser products to the U.S. in the future they must be in compliance with the standard. Therefore, to resolve this matter you must submit all the information required under

21 CFR 1002.10 so that CDRH can determine that your companies are in compliance with the Act, that the subjects products comply with the standard and that the testing program(s) are in accord with good manufacturing practices. The CDRH will inform you whether your submittal is satisfactory.

Submit your response to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. Should you have any questions on these requirements, please contact Frank Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Spears for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

ENC: Shipping Documents

CC: Importing Agent
Nahum Meir, President
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Mr. Thomas Wu
California Gift Center, Inc.
4334 South Santa Fe Ave
Vernon CA 90058

Division of Import Operations